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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,682	08/27/2001	David E. Townsend	150026.464	4343

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 6300  
SEATTLE, WA 98104-7092

EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/940,682

**Applicant(s)**

TOWNSEND, DAVID E.

**Examiner**

Allison M. Ford

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's Request for Continued Examination and amendment to the specification filed on 13 January 2005 have been received and entered into the case. Claims 1-7 and 10-16 are pending and have been considered on the merits. All arguments have been fully considered.

#### *Priority*

Acknowledgement is made of applicant's claim for priority to provisional application 60/228,956, filed 28 August 2000, priority under 119(e) is granted.

Acknowledgement is made of applicant's claim for priority as CIP to application 08/484,593, now US Patent 6,387,650, filed 7 June 1995, is not granted.

Priority under 120 is denied because the parent application does not disclose subject matter critical to the currently claimed invention; therefore the claimed invention was not enabled at the time of filing of the parent application. Specifically, the currently claimed invention requires a composition that comprises a conditionally detectable marker, wherein said marker is a red-ox dye, and a substrate that comprises a signal moiety linked to the substrate, wherein the signal moiety can be cleaved by non-target microorganisms to produce a detectable signal (Claim 1). Specifically, the conditionally detectable marker must be detectable by a change in color (Claim 6), and the change in color must be produced by the biochemical reduction of tetrazolium red (Claim 7). While 08/484,593 discloses a composition that comprises a substrate comprising a signal moiety linked to the substrate, wherein the signal moiety can be cleaved to produce a detectable signal, it does not teach or suggest inclusion of a conditionally detectable marker that is tetrazolium red, or any redox dye. Therefore the inclusion of a conditionally detectable marker that is a red-ox dye was added as new matter in the presently filed application. Because applicants did not have possession of the invention, as currently claimed, at the time of the filing of

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08/484,593 priority is not granted under 35 USC 120 for status of a CIP. However it is noted that complete disclosure of the invention is present in the provisional application 60/228,956, thus the effective filing date of the new matter in present claims 1-7 and 10-16 is determined to be the date of the provisional application, 28 August 2000.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 10-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend (WO 96/40980).

Applicant claims a composition for detecting a target microorganism, the composition comprising a conditionally detectable marker that is a redox dye, and a substrate for an aminopeptidase that is substantially absent from a target microorganism; wherein the substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aureus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change, wherein the change in color is produced by a biochemical reduction of tetrazolium red. The enzyme is specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically L-alanin-7-amido-4-methylcoumarin. The non-target microorganisms are substantially all non-Campylobacter species. The composition further

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comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organisms.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (pg. 11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers (pg. 7, claims) such as tetrazolium, phenol red, and neutral red (redox dye), which are chemically reduced to produce a color change (p. 2, 7, claims) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p. 6, 9), or are conditionally detectable markers. Bacteria are selected from Staphylococcus aureus, E. coli, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p. 8-9) (includes Salmonella, Listeria, Campylobacter, Cryptosporidium, S. aureus). Townsend teaches the claimed substrates (p. 19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (pg. 9). The composition further comprises the nutrients necessary to support growth of the microorganisms (pg. 3).

Although Townsend does not specifically teach the compositions comprising the claimed dyes, Townsend does teach the compositions to include color markers and that effective markers include tetrazolium, phenol red and neutral red. Therefore at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to use tetrazolium red or the redox dyes in the composition of Townsend with a reasonable expectation for successfully detecting microorganisms. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-7 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend in view of Stern.

Applicant claims a composition for detecting a target microorganism, the composition comprising a conditionally detectable marker that is a redox dye, and a substrate for an aminopeptidase that is

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substantially absent from a target microorganism; wherein the substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aureus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change, wherein the change in color is produced by a biochemical reduction of tetrazolium red. The enzyme is specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically L-alanin-7-amido-4-methylcoumarin. The non-target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism and antibiotics to suppress growth of non-target microorganisms.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (pg. 11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers (pg. 7, claims) such as tetrazolium, phenol red, and neutral red (redox dye), which are chemically reduced to produce a color change (p. 2, 7, claims) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p. 6, 9), or are conditionally detectable markers. Bacteria are selected from Staphylococcus aureus, E. coli, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p. 8-9) (includes Salmonella, Listeria, Campylobacter, Cryptosporidium, S. aureus). Townsend teaches the claimed substrates (p. 19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (pg. 9). The composition further comprises the nutrients necessary to support growth of the microorganisms (pg. 3).

Although Townsend does not specifically teach the compositions comprising the claimed dyes, Townsend does teach the compositions to include color markers and that effective markers include

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tetrazolium, phenol red, and neutral red. Therefore at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to use tetrazolium red or the redox dyes in the composition of Townsend with a reasonable expectation for successfully detecting microorganisms.

Townsend does not teach the composition further comprises antibiotics. However, Stern teaches compositions for detecting viable gram negative bacteria comprising antibiotics for suppressing other, non-target microorganisms (abstract). Stern teaches the inclusion of antibiotics allows the characterization of the target microorganisms (col. 1, ln 25-36). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Stern to include antibiotics in the composition of Townsend with a reasonable expectation for successfully detecting viable target bacteria. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### *Response to Arguments*

Regarding the rejection over Townsend alone, applicant asserts that the claimed invention is non-obvious over the cited reference, but fails to provide supporting arguments to this fact. Without support these arguments are not found persuasive.

Regarding the rejection over Townsend in view of Stern, applicant asserts that the claimed invention is non-obvious over the cited references and it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine the references, but fails to provide supporting arguments to this fact. Without support these arguments are not found persuasive.

### *Conclusion*

This is a RCE of applicant's earlier Application No. 09/940,682. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and

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art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

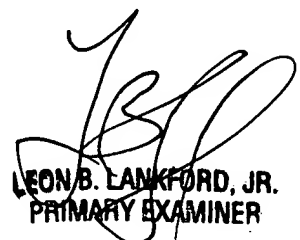
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford  
Examiner  
Art Unit 1651

  
**LEON B. LANKFORD, JR.**  
**PRIMARY EXAMINER**